Draft MoM Panel Questions

1. Although a significant amount of data regarding the performance and adverse events associated with Metal-on-Metal hip systems in peer-reviewed literature and joint registries come from US studies and populations, a large percentage come from outside the United States (OUS) sources. Please discuss the key differences, if any, between US and OUS practice which should be taken into account when reviewing/ interpreting the data, and which impact the ability to extrapolate OUS data to the US population, including differences in patient population, surgeon experience/preference/technique, and the devices themselves.

2. Based on published registry reports as well as information presented to the Panel today, please discuss the additional data fields which would be appropriate (and practical) to add to existing hip implant registries or include in new registries being developed.

3. For patients who have received a MoM Total Hip Replacement, but are *asymptomatic* (e.g., no pain, swelling, change in gait, new systemic signs/symptoms of metal toxicity, etc.) please discuss the optimal follow-up regimen(s) based on currently available information. **(70 MIN)**

   Specifically, please comment on:

   a. The frequency of follow-up with the orthopaedic and/or primary care physician.

   b. Which assessments should be included in the follow-up. Please specifically comment on
      i. Physical and/or functional examinations
      ii. Imaging assessments
      iii. Metal ion levels (including the source, e.g., serum, whole blood, urine)
      iv. Other laboratory tests
      v. Other assessments to evaluate for subclinical systemic manifestations

      In your discussion, please comment on whether the evaluations/tests should be done in any particular order and/or whether the decision to perform any test(s) is dependent on the results of other tests.

   c. Whether any finding, result, range of results or trend in results over time for the tests above should prompt an action or intervention including the need for more frequent monitoring or consideration for revision. In your discussion, please specifically comment on results of metal ion testing.

   d. Whether any particular patient or implant characteristic(s) - or combination thereof - would warrant follow-up different from your response above (e.g., more frequent follow-up, additional tests) and why. Please consider the following among others:

Patient Characteristics	Implant Characteristics
• Gender • Weight, BMI • Patient Age • Underlying disease or indication for initial implantation • Patient activity level/type	• Implant Age • Femoral head size • Acetabular cup position (inclination, anteversion) • Acetabular cup thickness and coverage • Diametrical clearance of components • Taper length • Unilateral vs bilateral implants

   e. Would any of the recommendations you made above change if the patient's MoM hip is not the index implant?

4. For patients who have received a MoM Total Hip Replacement and are *symptomatic* (e.g., pain, change in gait, swelling, new systemic signs/symptoms of metal toxicity, etc.) please discuss the optimal follow-up regimen based on currently available information. **(55 MINUTES)**

   Specifically, please comment on:

   a. The frequency of follow-up with the orthopaedic and/or primary care physician

   b. Which assessments should be included in the follow-up. Please specifically comment on
      i. Physical and/or functional examinations
      ii. Imaging assessments
      iii. Metal ion levels (including the source, e.g., serum, whole blood, urine)
      iv. Other laboratory tests
      v. Other assessments to evaluate for systemic manifestations

      In your discussion, please comment on whether the evaluations/tests should be done in any particular order and/or whether the decision to perform any is dependent on the results of other tests.

   c. Whether any finding, result, range of results or trend in results over time for the tests above should prompt an action or intervention including the need for more frequent monitoring or consideration for revision. In your discussion, please specifically comment on results of metal ion testing.

   d. Whether any particular patient or implant characteristic(s) - or combination thereof - would warrant follow-up different from your response above (e.g., more frequent follow-up, additional tests) and why. Please consider the following among others:

Patient Characteristics	Implant Characteristics
• Gender • Weight, BMI • Patient Age • Underlying disease or indication for initial implantation • Patient activity level/type	• Implant Age • Femoral head size • Acetabular cup position (inclination, anteversion) • Acetabular cup thickness and coverage • Diametrical clearance of components • Taper length • Unilateral vs bilateral implants

   e. Would any of the recommendations you made above change if the patient's MoM hip is not the index implant?

5. For patients who have received a MoM Hip Resurfacing System, but are *asymptomatic* (e.g., no pain, swelling, change in gait, new systemic signs/symptoms of metal toxicity, etc.) please discuss the optimal follow-up regimen based on currently available information. **(40 MINUTES)**

   Specifically, please comment on:

   a. The frequency of follow-up with the orthopaedic and/or primary care physician

   b. Which assessments should be included in the follow-up. Please specifically comment on
      i. Physical and/or functional examinations
      ii. Imaging assessments
      iii. Metal ion levels (including the source, e.g., serum, whole blood, urine)
      iv. Other laboratory tests
      v. Other assessments to evaluate for subclinical systemic manifestations

      In your discussion, please comment on whether the evaluations/tests should be done in any particular order and/or whether the decision to perform any is dependent on the results of other tests.

   c. Whether any finding, result, range of results or trend in results over time for the tests above should prompt an action or intervention including the need for more frequent monitoring or consideration for revision. In your discussion, please specifically comment on results of metal ion testing.

   d. Whether any particular patient or implant characteristic(s) - or combination thereof - would warrant follow-up different from your response above (e.g., more frequent follow-up, additional tests) and why. Please consider the following among others:

Patient Characteristics	Implant Characteristics
• Gender • Weight, BMI • Patient Age • Underlying disease or indication for initial implantation • Patient activity level/type	• Implant Age • Femoral head size • Acetabular cup position (inclination, anteversion) • Acetabular cup thickness and coverage • Diametrical clearance of components • Taper length • Unilateral vs bilateral implants

   e. Would any of the recommendations you made above change if the patient's MoM hip is not the index implant?

6. For patients who have received a MoM Resurfacing System and are *symptomatic* (e.g., pain, swelling, change in gait, new systemic signs/symptoms of metal toxicity, etc.) please discuss the optimal follow-up regimen based on currently available information. **(35 MINUTES)**

   Specifically, please comment on:

   a. The frequency of follow-up with the orthopaedic and/or primary care physician

   b. Which assessments should be included in the follow-up. Please specifically comment on
      i. Physical and/or functional examinations
      ii. Imaging assessments
      iii. Metal ion levels (including the source, e.g., serum, whole blood, urine)
      iv. Other laboratory tests
      v. Other assessments to evaluate for systemic manifestations

      In your discussion, please comment on whether the evaluations/tests should be done in any particular order and/or whether the decision to perform any is dependent on the results of other tests.

   c. Whether any finding, result, range of results or trend in results over time for the tests above should prompt an action or intervention including the need for more frequent monitoring or consideration for revision. In your discussion, please specifically comment on results of metal ion testing.

   d. Whether any particular patient or implant characteristic(s) - or combination thereof - would warrant follow-up different from your response above (e.g., more frequent follow-up, additional tests) and why. Please consider the following among others:

Patient Characteristics	Implant Characteristics
• Gender • Weight, BMI • Patient Age • Underlying disease or indication for initial implantation • Patient activity level/type	• Implant Age • Femoral head size • Acetabular cup position (inclination, anteversion) • Acetabular cup thickness and coverage • Diametrical clearance of components • Taper length • Unilateral vs bilateral implants

   e. Would any of the recommendations you made above change if the patient's MoM hip is not the index implant?

7. For patients being considered for primary hip arthroplasty, please discuss **(25 MINUTES)**
    a. Patient or population characteristics which are more likely to achieve the most favorable outcome and/or for whom the risks most likely outweigh potential benefits, with a
        i. MoM THR System
        ii. MoM Resurfacing System
    b. Pre-op laboratory or imaging tests which should be considered prior to implanting a MoM hip device.
    c. Pre- or intra-operative factors/findings which a surgeon should consider in identifying appropriate candidates for
        i. MoM THR
        ii. MoM Resurfacing System
    d. The critical elements of informed consent which are essential to convey to a patient considering MoM hip arthroplasty.

8. For patients undergoing device revision surgery, for any indication, please discuss the role of a MoM THR or Hip Resurfacing System as the secondary device for **(15 MINUTES)**
    a. Those whose primary implant is a MoM device (THR and Resurfacing)
    b. Those whose primary implant was not a MoM device (e.g., MoP, CoC)

9. Please discuss the key information which should be conveyed to physicians and/or patients as part of product labeling for MoM hip systems, including **(15 MINUTES)**
    a. Contraindications
    b. Warnings
    c. Precautions
    d. Directions for Use
    e. Outcomes Data
    f. Other